OIPE
JUN 28 2006
PATENT & TRADEMARK OFFICE
IAP1

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)
Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 600-1-081CON

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on June 28, 2006

Signature Loretta Kavanagh

Express Mail EV748266355US

Typed or printed name Loretta Kavanagh

Application Number	Filed
09/586,704	June 5, 2000

First Named Inventor: Steinman, et al.

Art Unit	Examiner
1644	Ronald Schwadron

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 52,491.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Veronica Mallon
Signature

Veronica Mallon, Ph.D.
Typed or printed name

201-487-5800
Telephone number

June 28, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Express Mail Label No: EV 748266355 US Dated: June 28, 2006

OIPE IAP1 JUN 28 2006 PATENT & TRADEMARK OFFICE

600-1-081CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Steinman *et al.* EXAMINER: Schwadron, Ronald B.

SERIAL NO.: 09/586,704 ART UNIT : 1644

FILED: June 5, 2000

FOR: IDENTIFICATION OF DEC, A RECEPTOR WITH C-TYPE LECTIN DOMAINS, NUCLEIC ACIDS ENCODING DEC, AND USES THEREOF

REMARKS LETTER FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AMENDMENT
COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VIRGINIA 22313-1450

Sir:

In the subject application, an Office Action dated July 22, 2005 rejected claims 26-28 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Subsequently, an Office Action dated March 23, 2006 again rejected claims 26-28, as well as newly added claims 35-45, under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The basis for maintaining the rejection was the same as that provided in the Office Action dated July 22, 2005. As such, the claims in the present application have been twice rejected and qualify for appeal. Accordingly, the following remarks are being submitted together with a Notice of Appeal under 37 C.F.R. § 41.31 in support of a Pre-Appeal Brief Request for Review.

Applicants believe the outstanding rejections of record are improper and without basis. In support of this position, Applicants present the following legal and/or factual deficiencies in the rejections.

Pending Claims

The pending claims under consideration are drawn to vaccines for inducing an immune response comprising an antigen conjugated to an anti-human DEC-205 antibody or an anti-murine DEC-205 antibody reactive with human DEC-205 protein, wherein the human DEC-205 protein comprises the amino acid sequence of SEQ ID NO:1. The amino acid sequence of SEQ ID NO:1 corresponds to a partial (C-terminal) sequence of human DEC-205.

The claims are further drawn to vaccines for inducing an immune response, wherein the vaccine comprises an antigen conjugated to an antibody which binds mouse DEC-205 having the amino acid sequence of SEQ ID NO:3, and wherein the antibody cross reacts with human DEC-205. The amino acid sequence of SEQ ID NO:3 corresponds to the full-length sequence of mouse DEC-205.

Rejections on Appeal

1. At page 3 of the Office Action dated March 23, 2006, claims 26-28 and 35-45 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the specification does not provide adequate written description of the claimed invention because, while the specification discloses the sequence of murine DEC-205 protein, the cloned human DEC-205 sequence referred is not disclosed. The Examiner asserts at page 4 (lines 10-13) that because human DEC-205 is approximately 1800 amino acids in length, the recitation in the claim of a 30 or 25 amino acid sequence derived from human DEC-205 does not provide adequate written description of a molecule that is almost 1800 amino acids in length. The Examiner notes at page 4 (lines 13-16) that the claims encompass antibodies that bind any immunogenic epitope on the approximately 1775 undisclosed amino acids of DEC 205.

2. At page 5 (lines 15-16) of the Office Action dated March 23, 2006, claims 26-28 and 35-39 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that there is no support in the specification for a human DEC-205 protein comprising an amino acid sequence as set forth in SEQ ID NO.:1. At page 5 (lines 17-20) the Examiner further

asserts that although the specification teaches that SEQ ID NO.:7 is a peptide derived from DEC-205, there is no support for a DEC-205 protein comprising the peptide wherein the molecule could have any amino acids in association with the aforementioned sequences recited in the claim.

Basis for Request for Pre-Appeal Review

From the outset, with respect to the Examiner's statements at page 5, paragraph 3 of the Office Action dated March 23, 2006, Applicants respectfully point out that none of the pending claims recite SEQ ID NO:7. Moreover, neither claim 6, nor claim 13 is currently pending. Accordingly, Applicants assume that the Examiner intended to refer only to SEQ ID NO: 1, as recited in claims 26 and 35.

With respect to the above-summarized § 112, first paragraph, rejections relating to claims 26-28 and 35-45, the mere fact that Applicants' specification does not recite the full length human DEC-205 sequence does ***not*** alone mean that the pending claims fail to comply with the written description requirement. As discussed at pages 9 and 10 of Applicants' Amendment and Response dated December 22, 2005[1], under current law, the standard for meeting the Written Description requirement differs for every patent specification depending upon a number of factors, including the ***scientific knowledge in existence at the time of the invention, the skill in the art, the predictability of the claimed subject matter***, and correlation of a described function to a known structure. *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

Applicants have fully met this standard. Specifically, ***the maturity of the science and skill in the art at the time of the present invention were such that one of ordinary skill could predictably obtain full-length proteins, such as DEC-205, based on partial sequences, as well as predictably obtain antibodies against the full-length protein (or any region of it***, as argued at page 10 (lines 15-18), of the Amendment and Response dated December 22, 2005.

Indeed, at the filing date of the present application (*i.e.*, in 1995), technologies for isolating, characterizing and cloning proteins were highly developed, as were technologies for generating antibodies against such proteins (see arguments at pages 10-11 of the Amendment and Response dated December 22, 2005). For example, several

[1] At page 2, paragraph 1 of the Office Action dated March 23, 2006 the Examiner refers to "Applicant's submission filed on 12/27/05." Applicants respectfully point out that an Amendment and Response was filed on December 22, 2005, not December 27, 2005.

well known techniques were available for cloning proteins, including human DEC-205, based on a given partial amino acid sequence of the protein. Additionally, techniques for expressing cloned proteins and for generating antibodies against the proteins were equally well known. Once armed with a partial amino acid (*i.e.,* a peptide derived from a given protein), it was also well within the skill of the art to use these techniques to generate antibodies against such peptides and to isolate the full-length protein from its natural source.

Applicants specifically illustrated this in relation to mouse DEC-205, as discussed at page 11 (lines 5-12) of the Amendment and Response dated December 22, 2005. In particular, Applicants successfully isolated and characterize full-length mouse DEC-205 from whole murine thymi using mAb NLDC-145, an anti-mouse DEC-205 antibody. Additionally, Applicants successfully raised antibodies against N-terminal peptides from mouse DEC-205 protein. This provides ***clear evidence*** that the partial human DEC-205 sequence described in the present disclosure put Applicants in possession of the complete DEC-205 protein and antibodies against the protein.

Additionally, in the present application, Applicants teach a partial (C-terminal) sequence (SEQ ID NO.:1) of human DEC-205 protein. Applicants further teach the highly homologous full-length sequence of mouse DEC-205 protein (SEQ ID NO.:3), along with an in-depth characterization of this protein (including its ability to deliver antigen to an active antigen processing compartment of dendritic cells). Applicants also describe well-known techniques for cloning proteins (including human DEC-205) based on a given partial amino acid sequence of the protein, expressing cloned proteins and generating antibodies against the proteins. Based on these teachings, it was well within the skill of the art to have generated anti-DEC-205 antibodies and the full-length human DEC-205 protein, as argued at pages 10-12 of Applicant's Amendment and Response dated December 22, 2005.

In fact, as discussed at page 11 (line 23-31) of Applicants' Amendment and Response dated December 22, 2005, and as evidenced by the Declaration by Dr. Michel Nussensweig and related publications submitted with Applicants' Amendment and Response dated January 3, 2005, the cloning techniques and techniques for generating antibodies described in the specification were ultimately successfully used to clone and isolate human DEC-205 and to produce antibodies against full-length human DEC-205.

This provides ***clear evidence*** that Applicants were in fact indeed ***in possession of the claimed invention*** based on the descriptive text provided within the four corners of Applicants' originally filed disclosure.

Finally, as discussed at page 12 (lines 1-8), of Applicants' Amendment and Response dated December 22, 2005, the Written Description requirement may be satisfied if the disclosed function of the claimed invention ***sufficiently correlates to a particular, known structure***. In the present case, the structure and function of human DEC-205 clearly correlates to that of mouse DEC-205, the characteristics of which (including full-length sequence) are described in detail in the present disclosure. Accordingly, the fact that Applicants provide an in-depth characterization of mouse DEC-205, including its full-length sequence, which correlates to human DEC-205, provides further basis for fully meeting the Written Description requirement, as argued at page 12, lines 8-17, of Applicant's Amendment and Response dated December 22, 2005.

In sum, the teachings set forth in Applicant's specification, in combination with the high level of skill and knowledge in the art at the time of the invention, and the proven predictability of the technologies involved in the invention, clearly satisfies the standard for Written Description according to the guidelines articulated by the CAFC in *Capon v. Eshhar* (CAFC 2005), and demonstrates possession of the claimed invention.

CONCLUSION

According to the foregoing, it is respectfully requested that the panel find:

(i) that all existing claims are in condition for allowance and that the application should pass to issue,

or in the alternative

(ii) that there is allowable subject matter in the claims and prosecution on the merits should be reopened with an appropriate office communication.

Respectfully submitted,

Veronica Mallon

KLAUBER & JACKSON
411 Hackensack Avenue
Hackensack, NJ 07601
(201) 487-5800

Veronica Mallon, Ph.D.
Agent for Applicant(s)
Registration No. 52,491